IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: **BRIMONIDINE PATENT LITIGATION**	**C.A. No. 07-md-01866 GMS**

THE EXELA DEFENDANTS' ANSWERING CLAIM CONSTRUCTION BRIEF

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INTRODUCTION

By proposing fragmentary claim construction proposals—singling out isolated words or phrases located in the disputed claim limitations—Allergan fails to recognize that it is the patent claim limitations, as a whole, that must be considered in claim construction. *See, e.g., Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1372 (Fed. Cir. 2003) (holding that the district court erred when it relied on "single words of the limitations, e.g., 'circuit,' as opposed to the limitations as a whole, e.g., 'a first interface circuit for receiving keyboard and cursor control device signals from the workstation'"); *See also United States v. Telectronics, Inc.*, 857 F.2d 778, 781 (Fed. Cir. 1988) (holding that the district court's interpretation of the term "avoid" based on the dictionary definition without regard to the rest of the limitation was in error). Allergan's claim-construction arguments scarcely touch on the intrinsic evidence, instead focusing on legally-irrelevant supposed advantages of its commercial Alphagan® products and on this Court's construction in an earlier litigation of the single word "about" in the '834 patent claims—not the entire claim limitations in dispute here.

The Exela Defendants' brief, by contrast, systematically addressed the disputed claim limitations through all aspects of the intrinsic evidence. Of particular importance, the Exela Defendants' proposed construction of "the composition having a pH of about 7.0 or greater" identified and incorporated a key piece of intrinsic evidence that Allergan has ignored: Allergan's clear and unmistakable disclaimer of any construction of this central limitation that encompasses compositions having a pH of about 6.8 or less. Responding to an Office Action, Allergan represented to the Patent Office that:

> [t]he present invention is the result of the **surprising finding** that increasing the pH of a brimonidine solution to **a pH of greater than about 7.0** leads to similar efficacy at a 25% lower

> concentration (from 0.2% (w/v) to about 0.15% (w/v) or less) **than is seen in a brimonidine solution at a pH of about 6.6-6.8**.[1]

In this argument, Allergan committed to a meaning of the limitation "the composition having a pH of about 7.0 or greater" that does not encompass a pH of about 6.8 or less. Allergan now urges this Court to adopt a construction that ignores the representations Allergan made to obtain the patent. This Court should reject Allergan's proposed construction. *See Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers"). The Exela Defendants quoted the above passage from the prosecution history in the Joint Claim Charts that the parties first submitted to the Court on May 16, 2008. But Allergan—engaging either in sandbagging or willful disregard of its own prosecution history admissions—chose not to address it anywhere in its brief. Allergan's scant discussion of the prosecution history conspicuously omits any reference to this passage. (*See* Allergan Br., D.I. 49, at 8.)

In the earlier *Alcon* litigation, this Court construed the word "about" within this limitation as "approximately," a fact the Exela Defendants pointed out in their opening claim construction brief. (*See* Exela Defendants Br., D.I. 48, at 12.) But Alcon, presumably because it had a different ultimate legal position in the case, never asked this Court to adopt a construction of the entire claim limitation that reflected Allergan's clear disavowal of claim scope in the above argument. And the construction of the entire limitation proposed by the Exela Defendants does not in any way conflict with this Court's prior construction of the term "about." Accordingly, the Exela Defendants request this Court to adopt their proposed construction for the reasons set forth in their opening brief.

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[1] Reply to Office Action mailed March 17, 2003 (Tab 6 at A0151).

Allergan also attempts to condense the entire claim limitation "A therapeutically effective aqueous ophthalmic composition comprising: up to about 0.15 (w/v) of [brimonidine] tartrate" to one term: "therapeutically effective." Allergan's construction gives no useful guidance as to the scope of this limitation. By contrast, the Exela Defendants' proposed construction provides the specificity and precision warranted by the language of the entire claim limitation and the intrinsic evidence.

ARGUMENT

I. Allergan's Reliance on the Court's Previous Adjudication of the Word "About" Ignores the Intrinsic Evidence and Fails to Fully Construe the Entire Claim Limitation "the Composition Having a pH of About 7.0 or Greater"

Allergan's proposed construction of the claim limitation "the composition having a pH of about 7.0 or greater" centers exclusively on the word "about," in isolation, without considering the broader intrinsic evidence. Allergan's approach is improper because the entire claim limitation "the composition having a pH of about 7.0 or greater" is before the Court. *See Apex Inc.*, 325 F.3d at 1372. Allergan's over-reliance on this Court's prior construction of "about" contravenes an important principle of claim construction: the entire claim must be interpreted with consideration of its full context. *See DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1324 (Fed. Cir. 2001) (holding that a court cannot look at the "ordinary meaning of a claim term in a vacuum. Rather, we must look at the ordinary meaning in the context of the written description and prosecution history").

Although this Court's prior construction of the word "about" is relevant to issues of claim construction, it should not be applied, mechanically, to the **entire** limitation at issue here. *See Genzyme Corp. v. Transkaryotic Therapies, Inc.*, 346 F.3d 1094, 1104 (Fed. Cir. 2003) (affirming this Court's claim constructions and holding that this Court properly construed the

phrase "chromosomally integrated" in a manner different than the broad textbook meaning reached in another district court case because the court in that case "did not confront a prosecution history and specification that conclusively limits the scope of the disputed claim terms"). And Allergan's over-reliance on context-dependant cases like *Merck & Co. v. Teva Pharms USA, Inc.,* 395 F.3d 1364 (Fed. Cir. 2005) disregards the prosecution history, contravening established Federal Circuit claim construction principles. *See Southwall*, 54 F.3d at 1576.[2]

The minimal portions of the intrinsic record that Allergan cited in its brief are selective and do not support Allergan's position. Allergan alleges that two instances in the specification show that the pH of the claimed brimonidine tartrate composition "having a pH of about 7.0 or greater" could be nonetheless acidic (i.e., is less than 7.0). Allergan is wrong on both counts.

First, Allergan points to a segment of the specification stating that the pharmaceutical "**carrier**"—e.g., the water-based solution—from which the brimonidine tartrate composition is ultimately formed may have a pH of "about 6 to about 9 or about 10, more preferably about 6 to about 8, and still more preferably about 7.5." (Allergan Br., D.I. 49, at 17.) This argument is a red herring. First, this portion of the specification does not in any way purport to define the term "the composition having a pH of about 7.0 or greater." Second, this section describes the pH of the "aqueous liquid carrier" **not** the pH of the actually claimed brimonidine **formulation**.

Allergan further strains to find support in Example 2. (Allergan Br., D.I. 49, at 17.) Example 2 refers to five samples that were "subjected to a range of pH's from about 7 to about

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[2] Allergan's argument that the term "about" must be given one identified construction throughout the claims assumes that its proposed method for breaking up the limitation in dispute—focusing on a single word in different whole limitations—is appropriate. (Allergan Br., D.I. 49, at 16.) Allergan's tact highlights the problem with its fragmentary approach: one of ordinary skill would not look at the separate limitations of the '834 patent as a series of isolated words, but as whole limitations, each requiring its own construction.

10."[3] Allegan argues that three pH measurements discussed in this Example are below 7.0 (e.g., 6.67, 6.68, and 6.93). (Allergan Br., D.I. 49, at 17.) Allergan's argument here too fails.

First, Example 2 describes a pH of "about 7," **not** a pH level of "about 7.0," a more numerically precise pH level. During prosecution, Allergan specifically amended its claims to change "a pH of about 7 or greater" to the more numerically precise pH of 7.0 (in which the pH is defined to the tenth decimal point). (*See* Exela Defendants Br., D.I. 48, at 16.)

Second, the Example does not clearly connect even the phrase "a pH from about 7 to about 10" with the numbers presented in the chart. The description "a pH from about 7 to about 10" appears to describe the pH values the formulations were "subjected to" at the beginning of the experiment,[4] while the pH values presented in the chart appear to relate to measurements taken at the conclusion of the experiment—after subsequent steps of at least 15-day storage followed by filtration.[5]

Moreover, Example 2 provides no teaching of the claimed invention. Example 2 discloses five different compositions that contain 0.2% brimonidine tartrate, as described in Table III. Thus, the reference to a pH of "about 7 to about 10" in this Example does not relate to the pH of the claimed 0.15% brimonidine tartrate formulation.

Finally, when Allergan reported the data in Figure 1 of the patent, Allergan again intentionally excluded all pH values below 7.0. Figure 1 is a graph of the data points taken from Example 2, purporting to show how the pH and levels of CMC of the 0.2% brimonidine compositions affect the compositions' solubility. Figure 1 does **not** show any pH levels below 7.0. All data points relating to the brimonidine compositions measured to have acidic pH levels

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[3] Col. 15:23-24 (Tab 5 at A0054).
[4] Col. 15:23-25 (Tab 5 at A0054).
[5] Col. 15:23-30 (Tab 5 at A0054).

were specifically excluded—making clear that Allergan regarded the scope of "about 7" to cover neutral or alkaline, and not acidic, pH levels.

Allergan failed to cite any place in the specification where the claimed 0.15% brimonidine tartrate composition is formulated at a pH less than 7.0. And this Court has previously recognized that the '834 patent specification teaches that "the claimed compositions enhance the effectiveness of brimonidine tartrate (and other alpha-2-adrenergic agonist components) by increasing its apparent water solubility **at pHs higher than neutral, or 7.0**." *Allergan, Inc. v. Alcon Inc.*, 2005 U.S. Dist. LEXIS 32436, at *11 (D. Del. Dec. 8, 2005) (emphasis added).

Allergan's one-word construction of the claim limitation "the composition having a pH of about 7.0 or greater" fails to account for Allergan's clear and unmistakable disclaimer of any compositions having a pH value of about 6.8 or lower during prosecution of the '834 patent. A court cannot construe a claim "to cover subject matter broader than that which the patentee itself regarded as comprising its inventions and represented to the PTO." *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349 (Fed. Cir. 2004).

In the first Office Action, the Examiner rejected the claims as obvious.[6] In its written reply to the Office Action, Allergan committed to a meaning of the limitation "a pH of about 7.0 or greater" that does not encompass a pH of below about 6.8:

> The present invention is the result of the **surprising finding** that increasing the pH of a brimonidine solution to **a pH of greater than about 7.0** leads to similar efficacy at a 25% lower concentration (from 0.2% (w/v) to about 0.15% (w/v) or less) **than is seen in a brimonidine solution at a pH of about 6.6-6.8**.[7]

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[6] Office Action mailed December 18, 2002 (Tab 6 at A0139-140).

[7] Reply to Office Action mailed March 17, 2003 (Tab 6 at A0151).

Allergan represented to the Patent Office and to the public that the claimed 0.15% brimonidine tartrate composition, having a 25% lower concentration of brimonidine than the prior art brimonidine solution, was differentiated from a brimonidine solution with a pH of **about 6.6-6.8—and that this difference in pH range was the basis for the invention.** Through these representations, Allergan made perfectly clear that it believed that the claim language specifying a brimonidine tartrate formulation "having a pH of about 7.0 or greater" did not include a brimonidine tartrate formulation with a pH range of about 6.8 or below.

Federal Circuit claim construction principles require courts to evaluate the meanings given to the disputed terms during prosecution, and to take into account clearly disclaimed subject matter. For example, in *Computer Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366 (Fed. Cir. 2008), the patentee sought a broad construction of the claim limitation "portable computer" to include a device with a built-in display and keyboard (e.g., a laptop). *Computer Docking Station Corp.*, 519 F.3d at 1372. The Federal Circuit affirmed the district court's construction of the term "portable computer" in accordance with the patentee's statements during prosecution that "would lead a competitor to believe that the patentee had disavowed coverage of laptops." *Id.* at 1379 (a patentee "cannot recapture claim scope disavowed during prosecution to prove infringement"). In reaching this holding, the court noted that the patentee distinguished its invention from devices with peripheral devices in a response to an Office Action:

> The Applicants' invention is a portable microprocessing system . . . **the microprocessor interfaces with several peripheral devices including a keyboard, display, modem, serial and parallel port devices, a power source, etc.**

Id. at 1376 (emphasis added). The applicants expressly listed a keyboard and display as peripheral devices. *Id.* Thus, the court reasoned, if the keyboard and display were built-in or attached to the housing like a laptop, these peripheral connections would not be necessary. *Id.*

Moreover, in *Microsoft Corp.*, the Federal Circuit affirmed the district court's narrow construction of patent claims covering "methods for simultaneously transmitting voice and computer data to a remote site over a telephone line." *Microsoft Corp.*, 357 F.3d at 1350-51. The Federal Circuit based its decision on the patentee's representation to the Patent Office in response to an obviousness rejection that "**[a]pplicants' invention . . . transmits the packets across a [standard telephone line] to a remote site** . . . ." *Id.* at 1349 (emphasis added). The Federal Circuit held that "[w]e cannot construe the claims to cover subject matter broader than that which the patentee itself regarded as comprising its inventions and represented to the PTO." *Id.* The court further reasoned that "[w]e have stated on numerous occasions that a patentee's statements during prosecution, whether relied on by the examiner or not, are relevant to claim interpretation." *Id.* at 1350 (*citing Laitram Corp. v. Morehouse Indus.*, 143 F.3d 1456,1462 (Fed. Cir. 1998) ("The fact that an examiner placed no reliance on an applicant's statement distinguishing prior art does not mean that the statement is inconsequential for purposes of claim construction"); *E.I. Du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1438 (Fed. Cir. 1988) ("Regardless of the examiner's motives, arguments made during prosecution shed light on what the applicant meant by its various terms")).

This Court addressed a similar issue in *Bayer Healthcare LLC v. Abbott Labs.*, 2005 U.S. Dist. LEXIS 21042 (D. Del. Sept. 26, 2005) . There, this Court held that Bayer clearly and unmistakably distinguished its invention (gears) from the accused products' mechanism (chains) based on the Bayer's representations to the Patent Office during prosecution of the patent in suit and its representations made in a related application. *Id.* at *24-25. In *Bayer*, the patent in issue claimed a rotatable tray with concentric inner and outer rings of reagent container stations. *Id.* at *3. The rotation of the outer ring was driven by an independent motor connected with a circular

gear, which in turn drove satellite gears. *Id.* The parties' dispute centered on the term "gear" in the relevant claims.

After considering the prosecution history of the patent, this Court adopted the claim construction of "gear" as "a toothed machine part . . . that meshes with another toothed part . . . **and which excludes a chain**." *Id.* at *26 (emphasis added). During prosecution, Bayer stressed that the cited references "failed to anticipate the specific gear structure of claim 6." *Id.* at *19. Then, after the patent issued, Bayer distinguished similar claims in a continuation application from a prior art reference that rotated the satellite gears using a chain. *Id.* at *25.

Much like the cases above, Allergan explicitly contrasted the prior art (brimonidine tartrate compositions with a pH of about 6.6 to 6.8) with its claimed brimonidine compositions having "a pH of greater than about 7.0." In so doing, Allergan clearly and unmistakably provided notice to the Patent Office and the public that the meaning of the limitation "the composition having a pH of about 7.0 or greater" does **not** encompass brimonidine solutions with a pH at or below about 6.8. *See Bayer*, 2005 U.S. Dist. LEXIS 21042, at *13 ("the prosecution history of a patent serves an important public-notice function because it is a written record of both the inventor's understanding of the invention, and the limitations the inventor may have placed on the invention in order to distinguish it from prior art").

This Court should adopt the Exela Defendants' proposed construction of this limitation for these reasons and the reasons set forth in their opening brief. (Exela Defendants Br., D.I. 48, at pp. 11-18.)

II. The First Element of Claims 1 and 10 Should Be Construed In Accordance With Its Plain and Ordinary Meaning as Confirmed by the Intrinsic Evidence

In its opening brief, Allergan suggests that the Exela Defendants' proposed construction of the entire limitation "a therapeutically effective aqueous ophthalmic composition comprising:

up to about 0.15% of [brimonidine] tartrate" seeks to reword the phrase "therapeutically effective" in a way "other than it is written." (Allergan Br., D.I. 49, at 18.) Allergan again misses the point. Unlike Allergan, the Exela Defendants seek the Court's construction of the entire limitation, not only the phrase "therapeutically effective."

The Exela Defendants' proposed construction of this limitation is solidly founded in the intrinsic evidence and captures the necessity that any brimonidine tartrate formulation recited in the claims be "therapeutically effective." This Court should adopt the Exela Defendants' proposed construction of this limitation for the reasons set forth in their opening brief. (Exela Defendants Br., D.I. 48, at pp. 8-11.)

CONCLUSION

For the foregoing reasons, and for the reasons set out in the Exela Defendants' opening claim construction brief, the Exela Defendants respectfully request that this Court enter an order construing the claim limitations of the '834 patent as proposed by the Exela Defendants in the parties' Revised Joint Claim Charts. (D.I. 46.)

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Dated: June 16, 2008

UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on June 16, 2008, I electronically filed the foregoing with the Clerk of Court using CM/ECF and caused the same to be served on the plaintiff at the addresses and in the manner indicated below:

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